

### **REMARKS**

Applicant submit this Amendment in response to an Office Action dated April 3, 2006. Claims 1-19 are pending in the application. Upon entry of the present amendment claims 10 and 14 – 16 will be canceled, without prejudice, and claims 1-9, 11-13 and 17-19 will be pending in the application. Claims 1 and 12 are independent claims. By amendment herein, claim 14 has been incorporated into claim 12. Reconsideration of the present application in view of the foregoing amendment and accompanying remarks is respectfully requested.

#### **Claim Suggestion**

Claim 12 has been amended in accordance with the Examiner's suggestion by replacing the phrase "wavelength below 340 nm" to read "wavelength less than 340 nm".

#### **Claim Rejections under 35 USC 112**

The Examiner has rejected claims 7, 9 and 10 under 35 USC 112, second paragraph, as being indefinite. In this regard, the end of claim 7 has been amended to read "...by disrupting one or more nucleic acids of the organisms."

Claim 9 has been amended to be dependent on claim 3, which provides an antecedent basis for the term, "photoactive compound". Also, the claim wording has been amended to remove the indefinite term "specific chemical adduct" and clarify the purpose of the excited photoactive compound in the method claimed.

Claim 10 has been canceled. It is respectfully submitted that these amendments obviate the Examiner's rejection under 35 USC 112.

### **Claim Rejections under 35 USC 102**

The Examiner has also rejected claims 12-19 under 35 USC 102(e) as being anticipated by US Patent Application Publication 2002/0015662 published on February 7, 2002, to Hlavinka. This publication discloses an apparatus and method for inactivation of pathogens in fluids, such as blood or blood products by adding a photosensitizer to the fluid and exposing the fluid/photosensitizer mixture to a "pulsed" light source, having a wavelength of preferably 280-550 nm. In contradistinction to the method claimed in claims 12-19 as amended herein, the Hlavinka publication does "not" teach the importance of using a light source being substantially monochromatic; or having a designated wavelength less than 340 nm; or utilizing a light source that is excimer-based, non-pulsed and non-laser. Applicant has disclosed in accordance with the inventions claimed herein the undesirability of using pulsed light; the undesirability of using conventional or laser light; and the undesirability of using light which is not monochromatic (see page 15, lines 12-22; and page 18, lines 9-10). Also, Applicant has disclosed the importance of the designated wavelength of the light falling within a narrow band of wavelengths that can be used in the claimed method herein, and how small differences in wavelength can have significant effects on cell function, pathogen inactivation and excitation of photochemical additives (see page 19, lines 13-15).

Suffice it to say that Hlavinka does not disclose or suggest the method claimed in claims 12-19 as amended and this rejection should be withdrawn.

### **Claim Rejections under 35 USC 103**

The Examiner has rejected claims 1, 2, 5, 7 and 8 under 35 USC 103(a) as being obvious from the disclosure of the Prodouz article in view of the teachings of US Patent 5,843,143 to Whitehurst, the Kogelschatz et al article and the Oppenlander article. The Prodouz article (discussed by Applicant under the section entitled "Background of related Art", at page 8, lines 1-12) discloses the use of UV pulsed XeCl excimer laser radiation (at 308 nm wavelength) to inactivate attenuated polio virus in blood platelets and plasma (see the Abstract or Summary at the top of page 589). The Examiner acknowledges that Prodouz does not disclose the use of a non-laser excimer-based light source as is required in claim 1 and claims directly and indirectly dependent thereon (i.e., claims 2-11). Also, Prodouz does not disclose or suggest using a light source that is excimer-based, non-laser and non-pulsed. Prodouz discloses that increased power levels of the pulsed laser did "not" result in greater viral inactivation, but resulted in increased damage to platelets and plasma proteins (see the Abstract at the top of page 589). This is "contrary" to the method claimed by Applicant and disclosed (see Page 17, line 19 to page 18, line 8), namely pathogen inactivation without deleterious effect to blood product components. Additionally, Prodouz briefly speculates in passing at the end of the article (see page 591, last sentence) that future procedures "may" require the use of photoactivating agents. There is no

teaching or suggestion as to how such photoactive compounds would be incorporated in a method for treating "complex fluids" as is claimed by Applicant, which utilizes non-pulsed, non-laser excimer-based monochromatic light having a designated wavelength of between 260-310 nm.

The Whitehurst patent discloses an incoherent or non-laser light source having a high intensity lamp that can provide monochromatic light and can be used for medical applications (e.g., photodynamic therapy). Whitehurst does not disclose using an excimer-based light source, and discloses generally useful light wavelengths preferably of 350-700 nm, and usually of 250-1100 nm (see patent column 1, lines 63-65). However, there is no disclosure or suggestion for treating complex fluids which utilizes non-pulsed, non-laser excimer-based monochromatic light having a designated wavelength of between 260-310 nm, as is claimed herein in claims 1, 2, 5, 7 and 8.

The Kogelschatz article discloses generally the use in various industrial applications (e.g., material deposition, metal deposition, photoetching, etc.) of high intensity excimer lamps providing incoherent UV and Vacuum UV radiation utilizing halogen or rare gas halide excimers mentioned in Table 1 (see page 30) having a wavelength range of 157-354 nm. There is no disclosure or suggestion for medical use generally, and more specifically in treating complex fluids as is claimed herein. Moreover, the light wavelength range disclosed in the article does not teach the critical range contained in the claimed method of Applicant, namely 260-310 nm. Also, the article does not teach or suggest the importance of using "non-pulsed" light as is

claimed herein; in contradistinction the article teaches that various types of discharge-driven excimer lamp light sources can be used for generation of incoherent excimer radiation, which use “pulsed” light (see article page 30, paragraph 2.2).

The Oppenlander article discloses the superiority of incoherent excimer lamps over mercury lamps as a radiation source in photochemical treatment of water, which is different from the “complex fluid” treated according to the claimed method herein. The article discloses the use of the excimer gases, Xe<sub>2</sub> and KrCl, which generate light wavelengths of 172 nm and 222 nm, respectively, which are outside of Applicant’s claimed range of 260-310 nm. Also, the article concludes (see paragraph connecting pages 504-505) that such excimer lamps could be generally useful in unspecified broader applications based on improved radiation efficiencies which utilize “pulsed” electrical stimulation of the dielectric barrier discharge. Again, this is in contradistinction to the claimed method of Applicant for treating a “complex fluid” which utilizes non-pulsed, non-laser excimer-based monochromatic light having a designated wavelength of between 260-310 nm.

In view of the above amendments and remarks, it is respectfully submitted that there is no suggestion or motivation to one skilled in the art from the Prodouz article to consult the Whitehurst patent, Kogelschatz or Oppenlander articles, either individually or in any combination, to come upon the claimed method of claims 1, 2, 5, 7 and 8. It is accordingly submitted that this rejection is overcome and should be withdrawn.

The Examiner has also rejected claims 1-5, 7 and 8 under 35 USC 103(a) as being obvious from the disclosure of the aforementioned Prodouz article in view of the teachings of the aforementioned Whitehurst patent, Kogelschatz and Oppenlander articles and as applied to claims 1, 2, 5, 7 and 8 in further view of the aforementioned Hlavinka US published patent application. The Examiner acknowledges that the combined disclosures of Prodouz, Whitehurst, Kogelschatz and Oppenlander do not teach the addition of a photoactive compound, a system for controlling the temperature or the mixing of the blood product to be decontaminated by the non-laser excimer-based light source. Additionally, none of these references disclose or suggest, by themselves or in any combination thereof, the use of a light source in the claimed methods which is "non-pulsed". It is respectfully submitted, in view of the above amendments and remarks, that there would be no motivation one having skill in the art to combine the teachings of these five cited prior art references as indicated by the Examiner to overcome the deficiencies previously discussed to come upon Applicant's methods claimed in claims 1-5, 7, 8 and 11. It is therefore respectfully submitted that this rejection has been overcome and should be now withdrawn.

The Examiner has rejected claims 1, 2, 5, 7 and 8 under 35 USC 103(a) as being obvious from the disclosure of the aforementioned Prodouz article in view of the teachings of the aforementioned Whitehurst patent, Kogelschatz and Oppenlander articles and as applied to claims 1, 2 and 5-8 in further view of US Patent 4,952,812 to Miripol et. al. (cited by Applicant in the Information Disclosure Statement filed on February 11, 2004) and the de With et. al. article. The Examiner has acknowledged the combined disclosures of Prodouz, Whitehurst,

Kogelschatz and Oppenlander do not teach leukoreduction wherein the first fluid component is a carrier fluid. Miripol discloses an apparatus and method for irradiating with UV (having a wavelength of 280-320 nm) a thin film or layer of blood product (e.g., blood platelet concentrate) containing white blood cells (i.e., leukocytes) to reduce the undesirable effects of the white blood cells in alloimmunized patients (i.e., leukoreduction). There is no disclosure or suggestion by Miripol with regard to using excimer-based light which is non-pulsed and non-laser and monochromatic, nor in the context of Applicant's method for treating "complex fluids" such as blood plasma that can contain other components such as carriers, one or more pathogens, and may incorporate in the complex fluid a photoactive compound prior to such light irradiation.

The de With article discloses that a single "pulse" laser light generated from an XeCl excimer at a 308 nm wavelength can break DNA strands of human lymphocytes in phosphate-buffered saline, wherein the lymphocytes were grown in a cell culture. There is no disclosure or suggestion by de With of Applicant's claimed method for treating complex fluids utilizing non-pulsed, non-laser excimer-based monochromatic light having a designated wavelength of between 260-310 nm.

It is respectfully submitted, in view of the above amendments and remarks, that there would be no motivation one having skill in the art to combine the teachings of these six cited prior art references as indicated by the Examiner to overcome the deficiencies previously discussed to come upon Applicant's methods claimed in claims 1, 2 and 5- 8. It is therefore respectfully submitted that this rejection has been overcome and should be now withdrawn.

Prompt action leading to an early Notice of Allowance is earnestly solicited. If the examiner believes a telephone communication might be useful in advancing prosecution of the application, the Examiner is invited to contact the undersigned representative of the Applicant.

Respectfully submitted,

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## CERTIFICATE OF MAILING

I hereby certify that the enclosed Amendment is being deposited with the United States Postal Service as first class mail, postage prepaid, addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on June 21, 2006.

Dated: June 21, 2006

Patty A. Hamilton  
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